Committee on Energy and Commerce

Subcommittee on Health

Hearing on "Examining Policies to Enhance Seniors' Access to Breakthrough Medical Technologies"

Thursday, September 18, 2025, at 9:30 a.m.

2123 Rayburn House Office Building

INTRODUCTION

Good morning, Chairman Guthrie, Ranking Member Pallone, Subcommittee Chair Griffith, Subcommittee Ranking Member DeGette, and distinguished members of the Committee. I am Todd Brinton, Chief Scientific Officer, and Corporate Vice President of Advanced Technology for Edwards Lifesciences. Edwards is the leading global structural heart innovation company, driven by a passion to improve patient lives. Through breakthrough technologies, world-class evidence and partnerships with clinicians and healthcare stakeholders, we deliver life-changing innovations to patients who need them most.

On behalf of Edwards, I would like to applaud the Committee for recognizing the importance of ensuring Medicare beneficiaries' access to life-saving breakthrough technologies. I'm honored to testify before this Committee for the second time in two years on this topic—an indication of how urgent and enduring the conversation around access to breakthrough medical technologies remains. I'm grateful for the opportunity to come back today and share our lessons learned over the past several years and how we can continue to support timely access to innovations for Medicare beneficiaries.

My perspectives and expertise are rooted in my background as both a clinician and innovator. I began my career as a biomedical engineer, inspired by generations of engineers in my family. But, after spending five years as an engineer in a start-up medical technology company, I chose to augment my experience and enroll in medical school. Upon completion of medical training, which included residency and three fellowships, I chose a career in interventional cardiology, spending 14 years on the faculty at Stanford University as a Clinical Professor of Medicine. During my time at Stanford, I witnessed countless patients facing life-threatening cardiovascular conditions with limited or no treatment options. These experiences underscored a painful truth: too often, patients must wait for access to new medical technologies that could save or transform their lives. This can be true for breakthrough innovations introduced for the first time or for established therapies treating new, or previously unreachable, patient populations. It is these same experiences that encouraged me to complete further training in medical technology innovation at the Stanford Mussallem Center for Biodesign. Ultimately, this invaluable training led me to also serve as a director for the center where I had the opportunity to teach and coach numerous individuals in the development of medical technology. With this same training, I also founded several cardiovascular companies, including one which went public and was ultimately acquired by Johnson & Johnson last year.

My journey led me to Edwards, where for the past six and a half years I've supported our mission to bring life-saving innovations to patients as quickly and responsibly as possible. We back this commitment with substantial investment in research and development—on average, 17% of our revenue is reinvested back into R&D, more than twice that of others in the industry. This allows us to pioneer first-in-class therapies that address critical unmet needs, particularly for nearly half of Medicare beneficiaries suffering from at least one cardiovascular condition.

Today, I will address three key topics to improve the Medicare coverage process for innovative technologies. First, I will highlight challenges with current Medicare coverage processes facing technologies across the innovation lifecycle. Second, I will share our experience under the Transitional Coverage for Emerging Technologies (TCET) coverage pathway for a recently approved breakthrough technology and offer my perspective on important learnings. And finally, I will share a specific example of how the NCD process should be modernized to reflect the continued maturation of technologies, using an example of the transcatheter aortic valve replacement, or TAVR, NCD that was established more than a decade ago.

CURRENT COVERAGE CHALLENGES ACROSS THE INNOVATION LIFECYCLE

The innovation lifecycle for medical technologies, from identifying an unmet clinical need to FDA authorization and widespread clinical adoption, is a rigorous, multi-year process. Yet even following FDA approval, Medicare coverage often lags, creating what many call the "valley of death" between regulatory approval and patient access. On average, it still takes over 5 years for an innovative technology to achieve effective Medicare coverage; this delay and uncertainty stifles innovation and, more importantly, denies beneficiaries' access to life-saving therapies. To close this gap, coverage frameworks must evolve to match the pace of innovation. Transitional coverage policies offer a promising bridge. These policies must be paired with clear post-breakthrough coverage pathways and an efficient NCD process to ensure continuity for beneficiaries.

TCET INSIGHTS AND RECOMMENDATIONS FOR BREAKTHROUGH COVERAGE

There has been broad interest among stakeholders, including bipartisan members of this committee, and across Administrations, to create a pathway for timely and transitional coverage of breakthrough therapies. Edwards had the opportunity to engage with CMS and test the process and concepts of the existing TCET pathway with our EVOQUE transcatheter tricuspid valve replacement technology.

EVOQUE is an example of a truly innovative and life-changing therapy for patients with no other treatment options. Patients with tricuspid regurgitation (TR) frequently suffer debilitating symptoms including difficulty breathing, lower extremity and abdominal swelling, and significant reductions in their quality of life. As one patient, Mary, described her experience with TR, she "was merely a fixture in [her] house" and "was barely existing" and asked her doctor how it would feel when she died. She was gripped by fear, hopelessness and despair. Following her tricuspid valve replacement with EVOQUE, she was able to laugh and breathe at the same time; laughter that quickly turned to cries of joy. She experienced a complete quality-of-life transformation, has more stamina, is able to reengage in her life, and dances with her kids and grandkids at every family gathering. Mary's story highlights how timely access to this breakthrough technology radically transformed her life. Edwards began our coverage journey to ensure access for EVOQUE to patients like this, under Parallel Review in 2020. In 2023, as we were preparing for FDA approval and engaging with CMS on coverage, the agency began testing its concepts of TCET.

Under TCET, CMS created a process to establish an NCD for innovative technologies, requiring evidence generation timelines along the way, with the goal of achieving an NCD shortly following FDA approval. CMS tested the processes and concepts of TCET by applying them to our coverage request for EVOQUE. The first step was an evaluation of the currently available evidence. The agency

identified gaps in the available clinical evidence at that point in time, which resulted in ongoing, collaborative discussions about designing a Coverage with Evidence Development (CED) study to fill such gaps, utilizing real world evidence. This was an iterative process in which the agency engaged in discussions on how our future evidence would answer questions relevant to the agency's eventual determination on durable coverage for transcatheter tricuspid valve replacement.

The NCD was finalized in March of this year and has already demonstrated the positive impact national coverage of breakthrough technologies can have on patient access. The NCD was implemented 13 months after EVOQUE was FDA approved. In the six months following the issuance of the final NCD, access continues to increase as more patients in need have been able to receive treatment. Positive coverage determinations have a profound impact on beneficiary access to breakthrough therapies; without this breakthrough coverage pathway, and CMS testing its' concepts, coverage for EVOQUE would be uncertain and beneficiary access would be in jeopardy.

Predictability in the Medicare coverage process is essential for innovators striving to deliver transformative technologies to patients with serious unmet needs. Our experience under a TCET pilot has yielded valuable insights to inform an expanded transitional coverage pathway, that is not limited to five technologies a year. According to data released earlier this week by CMS, in the one year since TCET was established, the agency has only accepted one technology in the pathway. Medicare beneficiaries deserve more timely access to breakthrough technologies. Edwards supports a legislative approach to establish a clear and reliable transitional coverage pathway for breakthrough designated devices. To achieve our shared goals of ensuring beneficiary access to the most transformative innovation and based on our experience as a TCET pilot, Edwards supports a breakthrough coverage pathway that incorporates the following features:

1. Extends coverage to breakthrough designated and FDA authorized devices at the time of FDA authorization that are within an existing Medicare benefit category.
2. Includes breakthrough designated technologies that received FDA authorization within the past two years preceding the implementation of the breakthrough coverage pathway.
3. Implements a robust enforcement mechanism to ensure Medicare Advantage plans provide consistent coverage of breakthrough technologies.
4. Prioritizes resources through increased funding and additional personnel within the Coverage and Analysis Group at CMS to enable access to technologies eligible for transitional coverage.

These principles allow CMS to allocate resources efficiently, foster innovation, and create greater predictability and transparency for innovators. Most importantly, it will ensure that Medicare beneficiaries, like Mary, have timely access to breakthrough therapies that can transform their lives. We are pleased to see that many of these principles are incorporated into the discussion draft before the committee today, and we look forward to working with members of the committee to advance this important bill.

MODERNIZING THE NCD PROCESS: TIMELY ACCESS TO MATURE THERAPIES

Accelerating coverage for breakthrough therapies is essential for technologies early in the innovation lifecycle; it is equally important to maintain coverage for existing innovative therapies used in clinical practice. Innovation is a powerful process and iterative force; it is not an end point. As such, many technologies continue to evolve through expanded indications, improved delivery methods, and new clinical evidence, yet the NCD process often lacks the agility to keep pace. Outdated coverage policies can unintentionally limit access to therapies that deliver meaningful outcomes to

Medicare beneficiaries. To ensure coverage reflects advancements in clinical practice and real-world data, Congress and CMS must work together to modernize and streamline the NCD process for established therapies.

As an example, Edwards has engaged productively with CMS and the FDA in advancing Transcatheter Aortic Valve Replacement (TAVR) technologies for more than a decade. TAVR is another transcatheter procedure that treats the debilitating disease of aortic stenosis (AS). AS describes a condition in which the heart's aortic valve narrows, restricting normal blood-flow resulting in shortness of breath, chest pain, low energy, lightheadedness and other symptoms. Medicare patients with AS can suffer up to 50 percent mortality at one year without treatment.

Our engagement with both the FDA and CMS began in 2007 with the series of PARTNER trials studying multiple generations of the SAPIEN valves, where we worked collaboratively to design and generate best-in-class evidence for TAVR. The TAVR NCD with CED was first issued in 2012 marking a significant milestone, allowing initial patient access to this life-saving treatment as technology, real-world evidence, and clinical experience evolved. In 2019, CMS updated the TAVR NCD to better reflect the available evidence and clinical practice, appropriately expanding beneficiary access and the number of qualified sites for these procedures.

While we've made important progress, today's AS patients face significant delays and obstacles in accessing TAVR, largely due to an outdated coverage policy and a cumbersome reconsideration process that has failed to keep pace with clinical advancements. AS remains largely undertreated, with less than half of the indicated patients receiving aortic valve replacement. Outdated and burdensome pre-procedural, peri-procedural, and infrastructure requirements for TAVR procedures

have contributed to these delays, adversely impacting patient outcomes. TAVR patients experience a two-month longer delay in treatment compared to the alternative open-heart surgical procedure, despite TAVR being a more cost-effective treatment option. The consequences of this delay are severe, with over 10% mortality at three months for patients on the TAVR waiting list. These delays are also costly to the Medicare program, with a one-year wait for TAVR costing an additional $10,000 per patient.

Although evidence to support the urgency of a TAVR NCD reconsideration is strong, Edwards is concerned that CMS' NCD process has slowed in recent years due to resource limitations and an outdated coverage process, which could delay the ability for the agency to meet the coverage needs of AS patients. Since 2003, the number of NCD requests completing the review process has declined annually by 25% and the length of time requests spend under review has increased by 56% overall. For mature technologies with robust evidence that have met CED requirements, we believe there are opportunities to streamline the NCD reconsideration process and resulting timeline that would relieve resource burdens for the agency and ensure that patients are not denied access to care.

Under the current NCD framework, reopening an existing NCD to update policy is often more challenging than it is to initiate a new NCD. Edwards recommends that Congress work with the agency to create efficiencies, improve transparency and predictability, and ensure sufficient funding to improve the reconsideration process. One example of an efficiency is to bypass the issuance of a tracking sheet and instead initiate the reconsideration process by posting a proposed decision memo. This approach would reduce administrative burden, maintain stakeholder engagement, and allow CMS to respond more efficiently to evolving clinical evidence—ultimately ensuring timely ac-

cess to life-saving therapies. We are pleased to see the committee considering legislation to improve NCD transparency and we look forward to working with the committee to update national coverage processes.

CONCLUSION

In conclusion, I commend members of this committee for proposing legislation to improve timely patient access to breakthrough technologies and to modernize the NCD process, and I urge the committee to move quickly to ensure Congress can enact meaningful change this year. Innovation alone is not enough—patients deserve a system that ensures these advances reach those who need them most. Together, we can shape a future where life-saving therapies are not delayed by bureaucracy, but delivered with urgency, compassion and scientific rigor.